

SEP 5 1996

510(K) SUMMARY

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1. Submitter:

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2. Trade name: NewMed ABP-lite

3. Common Name: Ambulatory Blood Pressure Monitor

4. Classification Name: Non-invasive blood pressure measurement system (per 21 C.F.R. § 07.1130)

5. The ABP-lite is substantially equivalent to the Nissei/NewMed ABP 1000i (Koven & Associates -- DS-240 -- K913595).

6. The ABP-lite is a 24-hour Ambulatory Blood Pressure Monitoring System (ABPMS) which obtains and stores the results of repeated determinations of blood pressure and heart rate during the activities of ordinary daily living. The ABP-lite system also manages a patient data base. The ABP-lite ABPMS includes a pneumatic cuff (worn by the patient), Data Recorder Unit (worn by the patient -- collects blood pressure ("BP") and heart rate ("HR") data), Remote Control Unit (LCD display of BP and HR data as well as error codes, patient control functions of event button and stop ongoing test), Interface Unit (interface between Remote Control Unit and PC), and ABPM-Soft Analyzer (proprietary custom software used for initial setup of Data Recorder, plus download, processing and printing of collected data).

The ABP-lite system weighs 13 ounces and is 21 cubic inches in size. The ABP-lite system uses the Korotkoff and oscillometric methods of blood pressure measurement with blood pressure cuff and microphone technology. Safety systems include an emergency pressure release system and watchdog timer.

7. The intended use of the ABP-lite is to detect, diagnose, and monitor hypertension.

8. The ABP-lite and the predicate device, the NewMed ABP 1000i are both used for the detection, diagnosis, and monitoring of hypertension. The two devices perform essentially the same functions in measuring BP and HR over a 24-hour period and utilizing a standard personal computer for downloading and displaying recorded data. The ABP-lite is lighter than the 1000i, and can take and store fewer readings over a 24-

hour period than the 1000i. The ABP-*lite* does not use ECG gating in measuring BP and therefore requires a lower complexity of software management. The ABP-*lite* stores acquired data on a computer chip whereas the ABP 1000i stores data on a cassette. Otherwise, the two devices perform identically.

9. Conclusions drawn from non-clinical testing performed on the ABP-*lite* blood pressure monitor are that the ABP-*lite* is substantially similar to the predicate device in intended use, target population, modalities of use, capacity for BP and HR range, and performance standards.
10. The ABP-*lite* contains software in the Computer Interface Unit and in the Data Recorder Unit. The software in the data recorder unit was designed using off-the-shelf software programs. The software in the Data Recorder Unit was custom configured.